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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,558	01/03/2002	Thierry Crost	02508.0092	2328

22852 7590 06/02/2005

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EXAMINER	
MENON, KRISHNAN S	

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,558	CROST ET AL.	
	Examiner	Art Unit	
	Krishnan S. Menon	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 2-25 are pending after the RCE of 5/13/05.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-14,21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 21 recites "... a semipermeable support base layer having pores and further comprising polyacrylonitrile and at least one anionic or anionizable group;". This limitation requires three different structures, the association of which is unclear: (1) a semipermeable support base layer having pores, (2) polyacrylonitrile (with or without pores) associated with the base layer, and (3) anionic or anionizable group associated with the support base layer (but may or may not be associated with the polyacrylonitrile). There is no support for this limitation in the specification or claims as originally filed. The specification (see abstract) discloses *"the support membrane is made essentially of a polyacrylinitrile, bearing anionic groups or groups capable of being anionic, the surface of the support semipermeable membrane designed to be in contact with blood or*

plasma is coated successively with a cationic polymer and an anticoagulant."

Therefore, the Examiner assumes that this limitation means 'a support membrane having pores, and made of polyacrylonitrile bearing anionic groups' for examination purposes.

Also, no support could be found on the limitation of claim 22, "said anionic groups avoid contact with the semipermeable support base layer", in the specification or claims as originally filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites the limitation "said anionic groups". There is insufficient antecedent basis for this limitation in the claim, since claim 21 recites anionic groups associated with the base layer as well as with the anticoagulant. The anionic group of the base layer cannot avoid contact with the base layer: *it is in the base layer.* Examiner assumes that the anionic group referred to in this claim belongs to the anticoagulant for examination purpose.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al (US 6,010,475) in view of Scholander et al (US 5,840,190).

Claim 21: Thomas teaches a semipermeable support base layer of polyacrylonitrile with anionic groups and having pores (col 4 lines 14-26), and a first coated layer of cationic polymer which bonds with the anionic groups, and which has associated steric hindrance to prevent from penetration into the pores of the base layer (col 6 lines 38-54: cationic macromolecule that does not enter the pores of AN69 membrane).

Claim 21 differs from the teaching of the reference in the limitation of a second coated layer of anticoagulant having anionic groups that form ionic bonds with the cationic groups of the first coated layer. Scholander teaches a heparin-coated membrane, heparin binds ionically with amino-groups on the surface – see col 5 lines 30-67. It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Scholander in the teaching of Thomas to have biocompatible membranes, especially in extracorporeal blood circulation, as taught by Scholander. One would use Scholander's teaching to modify the teaching of Thomas especially because of the advantages described in col 1 line 10 – col 2 line 3.

Claim 22: The anionic groups of the anticoagulant would not inherently be in contact with the anionic groups of the base layer in the references because of the intervening polyacrylonitrile.

Claims 2,3,4: anionic group is sulphonic; copolymer of acrylonitrile and methallyl sulfonate – see Thomas col 4 lines 15-20.

Claims 5-7: cationic polymer is polyethylene imine; quantity deposited – see example 1 of Thomas. (10 mg for 1.44 sq.m.)

Claim 8: cationic polymer is prepared by ultrafiltration, mol wt greater than the cutoff threshold - see example 1.

Claims 9, 10: glycoaminoglycans; heparin – see col 5 line 35 of Scholander

Claim 11: heparin coated in µg/sq.cm given in the examples of Scholander, are equivalent in range to the 200-20,000 IU/m2.

Claims 12-14: Thomas teaches the exchanger as claimed. See fig 1 and col 5 lines 1-48. Planar membrane – see col 5 lines 10-16.

Process claims 15-20 and 23-25: Thomas in view of Scholander teach the process as claimed, details of which are given under each claim below. The actual process steps in the teaching of Thomas in view of Scholander may not be in the same exact sequence as claimed. However, Selecting or changing order of process step is prima facie obvious. Ex parte Rubin , 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was

held to render prima facie obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.).

Claim 15: Thomas in view of Scholander also teaches a method of reducing the thrombogenic character of an exchanger by preparing a flat or hollow fiber membrane of acrylonitrile with anionic groups and having pores (see Thomas col 5 lines 1-53 and examples), fitting the membrane or bundle of hollow fibers, preparing the cationic polymer solution of cationic polymer large enough not to penetrate the pores of the base membrane (Thomas: col 5 lines 45-55), bring the solution in contact with the membrane, and then purging the solution of cationic polymer. Thomas does not teach the coating of the anticoagulant, but Scholander teaches coating of the anticoagulant, and then purge (or rinse) the anticoagulant solution – see examples of Scholander.

Claims 16 and 17: the rinsing of the membrane to remove the excess cationic polymer or the anticoagulant is taught by the references – example 1 of Scholander and col 5 lines 48-51 of Thomas.

Claims 18 and 19: sterilization before or after coating with the anticoagulating agent: Thomas in view of Scholander teaches sterilization – see Thomas example 1 or col 6 lines 55-60 or col 5 lines 44-47.

Claims 23 and 24: sterilization with gamma ray or ethylene oxide – see example 1 or col 6 lines 55-60 or col 5 lines 44-47 of Thomas.

Claim 25: Thomas in view of Scholander also teaches the method of preparing a composite semipermeable membrane by the steps of coating a semipermeable support base layer (col 5 lines 1-65 of Thomas, example 1 of Scholander), coating the cationic polymer solution, and then coating the anticoagulant solution.

Claim 20: Cationic polymer prepared by ultrafiltration to exclude chains capable of passing through the semipermeable support membrane – Thomas in view of Scholander does not teach this step of the process. However, Thomas teaches using polymer of molecular weight (or size) large enough that it does not enter the pores – see col 6 lines 45-55. The step of purifying the cationic polymer is not required since it starts with the purified polymer, or polymer of the required molecular weight. (Omission of an element and its function is obvious if the function of the element is not desired: Ex parte Wu , 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989))

Response to Arguments

Applicant's arguments filed 5/13/05 have been fully considered but they are not persuasive.

With re to the interview summary: Applicant's comment is acknowledged. The statement, 'motivation to combine:', was meant to represent applicant's question about the motivation to combine; and the examiner's response was that the motivation to combine could be found in the quoted lines, col 1 lines 15-33 of the Scholander ref.

With regard to the motivation to combine, Scholander provides an excellent reason to combine – preventing coagulation of the blood in short time exposure to foreign materials while oxygenating - by coating the surface of contact (ie., the membrane) with the anticoagulant. Col 1 line 10 – col 2 line 3. Applicant's argument about not having any motivation is not proper because Thomas teaches the apparatus for extracorporeal blood circulation; extracorporeal circulation would create the coagulation problems described by Scholander.

Re the Thomas'013 patent being of common assignee: this reference is withdrawn, and therefore the argument is moot.

Re the arguments about Thomas'475 in view of Scholander and the newly added limitations in the new claim 21, "steric hindrance" and 'preventing penetration into the pores', these are addressed in the rejection.

Re the arguments about claim 25, consecutive steps, this also is addressed in the rejection.

With respect to the 'article' that provides additional evidence that *one of ordinary skill in the art would not have attempted to combine because the article teaches that treating a biological surface with a cationic polymer [sic, surfactant] is known before treatment with heparin, and that the cationic surfactant would slowly release in blood, which is problematic, and applicant uses a cationic polymer*: This argument is not persuasive because the Thomas reference also uses the same polymer, and Scholander teaches polyethylene imine as the 'typical' surface modifying compound (col 5 lines 5-7).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Krishnan S. Menon
Patent Examiner
5/27/05